



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MERCHAV, SHOSHANA ET AL.

Serial No.: 09/890,401

Filed: 07/31/2001

**For: METHOD AND APPARATUS FOR
MAINTENANCE AND EXPANSION**

Group Art Unit: 1651

Attorney
Docket: 01/22310

Examiner: NAFF, DAVID M

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313

DECLARATION OF DR. SHAI MERETZKI UNDER 37 CFR 1.132

I have received my Ph.D. degree from the Technion Israel Institute of Technology and I am presently employed as CTO of Pluristem Life Systems Inc.

My research focuses on hematopoietic stem cell expansion. Since the beginning of my career and I have presented my achievements at many international scientific conferences.

I am a co-inventor of the subject matter claimed in the above-referenced U.S. patent application.

I have read the Official actions issued with respect to the above-identified application.

In this Official action, the Examiner has rejected claims 1-20 and 51-70 under U.S.C. § 103 as being unpatentable over Naughton et al. in view of Sussman et al. and Stephanopoulos et al.

The Appendix section enclosed herewith, which presents recent results obtained in our lab, illustrates that expansion of undifferentiated hematopoietic stem cells and progenitor cells requires high density 3-D stroma cells culture which can be exclusively achieved in a growth system containing medium flow and not in static culturing conditions in which the material transfer is based on diffusion and are described in the referenced prior-art.

These results conclusively demonstrate the advantages of the present invention over prior art culturing methods, thereby providing evidence that the rejections of claims 1-20 and 51-70 under U.S.C. § 103 are unfounded.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

18 December 2003
Pluristem
Life Systems, Inc.

Dr. Shai Meretzki

Pluristem Inc.

Enc.:

CV of Shai Meretzki and Appendix

SHAI MERETZKI, Ph.D.**Personal Information**

- Date/town of birth: 1969, March 17th, Haifa, Israel.
- Married; three children.
- Resident address: 38 Raul wallenberg St. Israel.
- Tel: 04-8347174, 050-277781
- E-mail: m_shai@netvision.net.il
- Israeli citizenship

Education

- 1999-2002 **Ph.D.** in Biotechnology
Technion-Israel Institute of Technology, Haifa, Israel.
Research was performed at the Haemopoiesis Unit, Rappaport Faculty of Medicine, under the supervision of Dr. Avinoam Kaduri & Prof. Dov Zipory from the Weizman Institute of Science, Rehovot, Israel and Dr. Shosh Merchav from the Technion.
Ph.D. Project: "Stationary packed bed bioreactor for propagation of transplantable human haemopoietic stem cells".
Graduation grade - 94.
- 1996-1999 **M.Sc.** The Interdepartmental Program in Biotechnology
Technion, Haifa, Israel.
- 1992-1996 **B.sc.** The Department of Chemical Engineering
Technion, Haifa, Israel.
- 1992-1996 **B.sc.** The Department of Biology
Technion, Haifa, Israel
- 1981-1987 High School - The Hebrew Reali School, Haifa, Israel

Employment

- 2003 CTO - Pluristem Life System
MATAM Advanced Technology Park, Haifa, Israel
- 2001-2002 Biological and chemical R&D - Polyheal Ltd.
Nesher, Israel.
- 1997-2001 Instructor - medical students Cell Biology and Hematology
Rappaport Faculty of Medicine, Haifa, Israel
- 1995-1996 The Department of Chemical Engineering – Technion
Haifa, Israel

Shai Meretzki, PhD

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Military Service

1987-1991 I.D.F. armed forces officer
Military rank: captain

Publications:

- Meretzki S, Kadouri A, Zipori D, Merchav S. (1998). "Maintenance and Expansion of Human Cord Blood Primitive Progenitor on Murine Stromal Cell Line." Acta Hematologica 100:20 (Abs).
- Patent: "Method and Apparatus for Maintenance and Expansion of Hemopoietic Stem Cells and/or Progenitor Cells". Publication no: WO 00/46349, August 2000.
- Meretzki S, Kadouri A, Merchav S. (2001). "Effect of Three Dimensional Stromal Cell Cultures on the Expansion of Transplantable Human Hematopoietic Stem Cells." ISHAGE 2001:41 (Abs).
- Meretzki S, Broyl A, Lapidot T, Merchav S. "Comparative Studies of the Effect of Various Stromal Cells on the Maintenance/Expansion of Human Cord Blood Stem Cells." (In press).
- Meretzki S, Kadouri A, Lapidot T, Silvian-Drachsler I, Frolov L, Merchav S. "Effect of Stroma Based Bioreactor on the Expansion of Transplantable Human Hematopoietic Stem Cells." (In press).
- Meretzki S, Kadouri A, Zipori D, Frolov L, Merchav S. (2003). "The Use of 3D Stromal Cell Cultures for the Propagation of Human Hematopoietic Stem Cells (HSC) ASH 2003:3119 (Abs).

Scholarship

1996-2002 Technion Scholarship

2001 Gutwirth Scholarship

2001 Technion Scholarship for presentation at 2001 ISAGE meeting
International Society for Hematotherapy and Graft Engineering
Quebec, Canada

1998 Gutwirth Scholarship

1998 Technion Scholarship for presentation
Molecular Biology of Hematopoiesis Convention
Bormeo, Italy